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TITLE: Robotic Surgery Readiness (RSR): A Prospective Randomized Skills Decay Recognition and Prevention Study

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

We have completed the study design and skill decay model construction. Supply purchasing and acquisition for all four sites was also completed during this period. Working with four different sites brought challenges and a good set-up and flow within and between simulation centers was necessary. We worked closely with our data collection group to develop robust methods for collecting, merging and verifying simulator, video and optical tracking data. Subjects continue to be recruited and many have completed the proficiency phase of this project and will be moving on to AIM 1.

15. SUBJECT TERMS

Robotic Surgery, Readiness, da Vinci Simulator, Virtual Reality, Simulation Curriculum, GEARS - Global Evaluative Assessment of Robotic Skills, Surgical Education

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1. INTRODUCTION:

We will establish the performance signatures of Robotic Surgery Readiness (RSR) through tasks on the da Vinci robotic virtual reality simulator by testing the role intervals of inactivity have on task performance. These signatures will be used to develop a simulation curriculum that brings the inactive surgeon to RSR. The curriculum effectiveness will be tested in the operating room on practicing surgeons performing patient surgery with and without the RSR warm-up curriculum. We will enroll surgical residents and faculty for hypothesis testing. Objective technical performance and Global Evaluative Assessment of Robotic Skills (GEARS) scoring will be correlated by the Principal Investigator (Dr. Thomas Lendvay - UW) and Co-Investigator (Dr. Timothy Kowalewski - UMN). Optimal methods for extracting surgeon performance metrics from the da Vinci Application Programming Interface (API) will be evaluated and developed through collaboration with the Intuitive Surgical Consultant (Simon DiMaio, Senior Research Manager). We will deliver practical, automated RSR assessment methods and a warm-up curriculum able to bring a robotic surgeon to his/her optimal state of readiness before patient surgery.

2. KEYWORDS:

Robotic Surgery
Readiness
da Vinci Simulator
Virtual Reality
Simulation Curriculum
GEARS - Global Evaluative Assessment of Robotic Skills
Surgical Education

3. ACCOMPLISHMENTS:

What were the major goals of the project?

YEAR 1 (0-12 Months)
1) Study design and skill decay model construction, supplies purchasing and acquisition. (0-3 months) *Completion date 9/30/2015, major supplies purchased thru 6/30/2016*
2) Set-up and flow within and between simulation centers. (0-3 months) *Completion date 9/30/2015*
3) Development of robust methods for collecting, merging and verifying simulator, video and optical tracking data. (0-6 months) *Completion date 12/31/2015. Continued checks as more equipment comes online. Tool motion metric capturing technology development – ongoing.*
4) Subject recruitment. (3-9 months) *Recruitment has begun at 3 of the 4 sites. 50% complete*
5) Skills decay testing. (3-12 months) *Several subjects will begin in the next quarter.*
6) Independent video review of VR simulator criterion performances using GEARS tool. (9-12 months)
7) Analysis of performance metrics. (9-15 months)

   Deliverables: Quantifiable performance signatures of robotic surgery skills decay assessment. Initial analysis of data. Preliminary RSR warm-up curriculum.

YEAR 2 (12-24 Months)
1) Finalize and validate RSR curriculum and benchmarks. (12-15 months)
2) Intra-operative RSR warm-up subject recruitment. (12-24 months)
3) RSR curriculum hypothesis testing, intra-operative data collection. (15-24 months)
4) Independent video review of surgical performances using GEARS. (18-24 months)

   Deliverable: Finalized RSR warm-up curriculum, initial dataset and data quality assessment.

YEAR 3 (24-36 Months)
1) Continued intra-operative RSR curriculum hypothesis testing. (24-33 months)
2) Continued independent video review of operative performances using GEARS. (24-33 months)
3) Biostatistical analysis and model cross-validation. (30-36 months)
4) Abstract and manuscript drafting. (33-36 months)

   Final Deliverables: Completed, validated RSR warm-up curriculum and assessment tools. Methodology for quantifying robotic surgery skills decay. Peer-reviewed publication, presentation at national meeting.

What was accomplished under these goals?

YEAR 1 (0-12 Months)
1) Study design and skill decay model construction, supplies purchasing and acquisition. (0-3 months)
   Study design and skills decay model completed by month 3 while acquiring major equipment has taken the entire first year but is now complete.
   Computers have been purchased and setup for all sites (UW, MAMC, VA, FL Hospital)

2) Set-up and flow within and between simulation centers. (0-3 months)

   As subjects are recruited they will complete the intake demographics questionnaire and complete the proficiency training. Subject identifiers/details will be kept at each site and only de-identified data will be collected by the team at Minnesota (UMN). All subjects will be given a unique identifier based on their location. Work with a UW biostatistician has helped move the data intake and form development along. RedCap is now being used to collect data and to randomize the subjects. We are getting all site coordinators trained on RedCap. (Figures 1 & 2, Appendix) All de-identified video and simulator data output is being collected by the team at UMN for analysis.(Figure 3, Appendix)

3) Development of robust methods for collecting, merging and verifying simulator, video and optical tracking data. (0-6 months)

   UMN has reworked the software to provide high definition video acquisition and compression (previous versions had poorer resolution and video artifacts).
   UMN has successfully installed and monitored the acquisition of data from all sites. The data is synchronizing with our central database as designed. Collaborative agreement between UMN, UW, and Intuitive Surgical, Inc. is on-going to extract tool motion metrics from da Vinci robot.

4) Subject recruitment. (3-9 months)

   Aim 1 Recruitment (RSR Curriculum design) has begun at 3 of the four sites. MAMC has 15 contacted, 9 subjects consented and 6 have completed their proficiency stage. UW/VA has 45 contacted with none proficient. Fl Hospital have none as of yet (Florida Hospital and UW needed to reconcile contract language before proceeding). MAMC has been able to act as our test site to confirm that our planning has worked. This has allowed us to edit forms and procedures to make the work flow optimally.

5) Skills decay testing. (3-12 months)

   MAMC has 6 ready to be randomized and begin Aim 1.

What opportunities for training and professional development has the project provided?

All of our Aim 1 participants are provided training in robotic surgery simulation activities in order to meet proficiency. This has been accomplished through peer and one-on-one training with an expert. The Proficiency Training introduces novices and hones experienced clinicians in robotic object transfer, suturing, management of the third working arm, camera and instrument clutching skills. We have not provided "Professional development" opportunities.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

YEAR 1 (0-12 Months)
3) Development of robust methods for collecting, merging and verifying simulator, video and optical tracking data. (0-6 months)

UMN continues to renegotiate the tri-party collaborative agreement with Intuitive Surgical and University of Washington. This was unavoidable but currently does not impede the progress of proficiency testing phase or Aim 1.

4) Subject recruitment. (3-9 months)

Subject recruitment has begun. Invitation emails have been sent. Proficiency training has begun at MAMC, UW and VA. Get Florida Hospital up and running.

5) Skills decay testing. (3-12 months)

Skills decay testing will begin with the consented subjects. Data acquisition will be continually monitored by UMN team.

4. **IMPACT:**

    What was the impact on the development of the principal discipline(s) of the project?

    We have developed a video and data capture system that allows remote software updates on each site's computer. (Figure 3, Appendix) This has minimized the need for any on-site software/hardware servicing. Furthermore, a workable user-interface was developed so that each site's coordinators can seamlessly capture video and upload data.

    What was the impact on other disciplines?

    A method for reliable seamless video capture, data tagging, and storage has a universal application in any training and skills assessment programs.

    What was the impact on technology transfer?

    Nothing to report.

    What was the impact on society beyond science and technology?

    Nothing to report.

5. **CHANGES/PROBLEMS:** *:*

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

As this is a multisite project problems were anticipated. We had some delays in IRB approvals at the VA but this was resolved and the IRB was approved. We had some delays in funding some of the sites. Due to the nature of funding a military site and the need for all funds to be used within that fiscal year we had to bring back the money allocated to MAMC and fund any manpower hours required centrally. The funding contract with Florida Hospital took longer than anticipated but was able to be worked out. Specifically, the University of Washington (a state-funded institution) was prohibited from providing a sub-contract to an institution that did not have an Equal Opportunity Employment (EOE) clause (Florida Hospital). This was resolved and the sub-contract was granted.

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals.

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

Publications, conference papers, and presentations

Nothing to Report

Journal publications.

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

Nothing to Report

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Name: Thomas Lendvay
No change

Name: Karen Edwards
No change

Name: Anna French
No change

Name: Prof. Tim Kowalewski
No Change

Name: Sara Teller
Project Role: Project Manager/Site Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Project management and subject management

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to Report

What other organizations were involved as partners?
Nothing to Report

8. **SPECIAL REPORTING REQUIREMENTS**
   COLLABORATIVE AWARDS:

   Nothing to Report

   QUAD CHARTS:

   Submitted

9. APPENDICES:

Record ID	
1) Age: * must provide value	
2) Gender: * must provide value	○ Male　○ Female　○ Other reset
3) Please select the category that most accurately reflects the participant's seniority: * must provide value	○ Junior (R1-R3) ○ Senior (R4-R8) ○ Attending (Fellow/Staff) reset
4) If Staff, how many years have you been out of training?	
	○ Currently a Fellow reset
5) If not Staff, please select your current year in training:	[　▽]
6) Surgical speciality: * must provide value	○ Urology　○ Gynecology　○ General Surgery reset
7) Experience with robotic surgery (# cases as primary surgeon, all time): * must provide value	 If no experience, please record 0.
8) Experience with laparoscopic surgery (# cases as primary surgeon, all time): * must provide value	
9) Handedness * must provide value	○ Left　○ Right　○ Ambidextrous reset
10) Do you have musical experience? * must provide value	○ Yes　○ No reset
11) If yes, what type of instrument do you play?	☐ Brass ☐ Percussion ☐ Strings ☐ Woodwinds ☐ Keyboard
12) If yes, how many years have you played an instrument?	
13) If yes, how often do you play an instrument?	○ Daily ○ Weekly ○ Monthly ○ Rarely ○ I no longer play any instruments reset
14) Have you ever been deployed or on civilian leave for an extended amount of time? * must provide value	○ Yes　○ No reset
15) Date of return from last deployment/ civilian leave/sabbatical (if applicable):	[　📅] [Today] Y-M-D
16) Duration of deployment/leave/sabbatical in months:	
17) Did you perform surgery while you were deployed or on leave?	○ Yes　○ No reset
18) Percent of time in the operating room (not in an administrative role) while deployed or on leave:	 Report value between 0 and 100
19) Days since last performed robotic surgery * must provide value	 If no experience, please record 365.
20) Days since last simulation/practice * must provide value	

Figure 1: Demographic form in RedCap

NOTE: Please be aware that branching logic and calculated fields will not function on this page. They only work on the survey pages and data entry forms.

This form should be completed for each module where proficiency goal is reached.
Modules 1-3: Each task must be completed with a goal of overall score of 90% or more.

Ring and Rail 2

Score reached?
* must provide value
○ Yes ○ No
reset

Score:

Date 90% score reached:
📅31 Today Y-M-D

Match Board 3

Score reached?
* must provide value
○ Yes ○ No
reset

Score:

Date 90% score reached:
📅31 Today Y-M-D

Suture Sponge 3

Score reached?
* must provide value
○ Yes ○ No
reset

Score:

Date 90% score reached:
📅31 Today Y-M-D

Module 4: The Cont. Suture task must be completed with proficiency goal of 78 seconds or less.

Continuous Suture

Time achieved?
* must provide value
○ Yes ○ No
reset

Time (in seconds):

How was this module timed?
○ Simulator
○ Researcher stopwatch
○ Peer stopwatch
reset

Date that time goal was reached:
📅31 Today Y-M-D

Proficiency achieved?
* must provide value
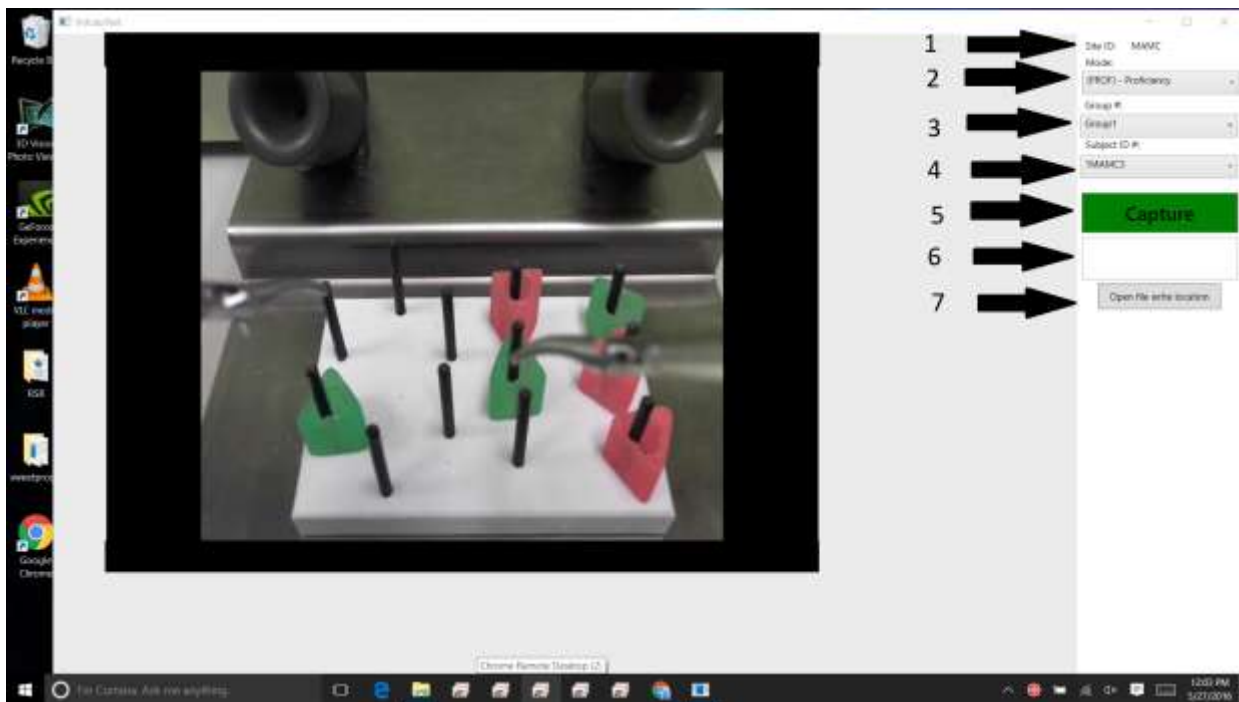○ Yes ○ No
reset

Date:
* must provide value
📅31 Today Y-M-D

Figure 2: Proficiency Form in RedCap

Figure 3: Video Capture Interface